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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,191	03/24/2004	Ronald M. Wallach	49386//58967 CON 2 (US)	4586
21874	7590	01/26/2005	EXAMINER	
EDWARDS & ANGELL, LLP			MARMOR II, CHARLES ALAN	
P.O. BOX 55874				
BOSTON, MA 02205			ART UNIT	PAPER NUMBER
			3736	
DATE MAILED: 01/26/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/808,191

Applicant(s)

WALLACH, RONALD M.

Examiner

Charles A. Marmor, II

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed November 12, 2004. The Examiner acknowledges the amendments to the specification, the amendment to claim 1, and the addition of new claims 2-6. Claims 1-6 are currently pending.

Terminal Disclaimer

2. The terminal disclaimer filed on November 12, 2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of prior patent No. 6,740,049 has been reviewed and is NOT accepted.

The person who signed the terminal disclaimer is not recognized as an officer of the assignee, and he/she has not been established as being authorized to act on behalf of the assignee. See MPEP § 324.

An attorney or agent, not of record, is not authorized to sign a terminal disclaimer in the capacity as an attorney or agent acting in a representative capacity as provided by 37 CFR 1.34 (a). See 37 CFR 1.321(b) and/or (c).

Claim Objections

3. Claim 1 is objected to because of the following informalities: in line 7, "the first end bristle portions" apparently should read --the first bristle end portions--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Bayne ('992).

Bayne teaches a cervical cytology device **42** including a plurality of elongated flexible bristles **50** of approximately uniform length connected to a handle including an elongated portion **46** and a head portion **48** to form a mop-like sample collecting member. The bristles extend from the head portion in a direction that is substantially parallel to the longitudinal axis of the handle. The head portion and the elongated portion are substantially cylindrical and the head portion is of a greater diameter than the elongated portion. The bristles have a modulus of elasticity that forms a soft surface having a substantially symmetrical shape.

6. Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Peltier ('087).

Peltier teaches a cytology brush for cervical or vaginal sampling. The brush **3** includes a plurality of elongated flexible bristles of approximately uniform length (at least those aligned with the elongated portion of the handle) connected to a handle including an elongated portion and a head portion to form a mop-like sample collecting member (see Fig. 1). The bristles

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extend from the head portion in a direction that is substantially parallel to the longitudinal axis of the handle. The head portion and the elongated portion are *substantially* cylindrical and the head portion is of a greater diameter than the elongated portion. The bristles have a modulus of elasticity that forms a soft surface having a substantially symmetrical shape.

7. Claims 1-3, 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Fomby ('988). Fomby teaches a brush that is capable of obtaining a sample from a body cavity. The brush includes a plurality of elongated flexible bristles of approximately uniform length connected to a handle including an elongated portion and a head portion to form a mop-like sample collecting member. The bristles extend from the head portion in a direction that is substantially parallel to the longitudinal axis of the handle. The head portion and the elongated portion are substantially cylindrical. The bristles have a modulus of elasticity that forms a soft surface having a substantially symmetrical shape.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially-created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-5, 9 and 10 of U.S. Patent No. 6,740,049.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim of the instant application is merely broader than that of the patent.

Regarding claim 1, both the claims of the patent and the claim of the instant application recite a device for obtaining a sample from a body cavity including a plurality of elongated bristles of approximately uniform length connected to a handle to form a mop-like sample collecting member, where the bristles are disposed in a direction parallel to the longitudinal axis of the handle. Claim 1 of the patent also provides additional limitations further defining the handle of the sample collecting device which are not recited in claim 1 of the instant application. Since claim 1 of the patent "anticipates" the broader claim of the instant application, the claims are not patentably distinct. The subject matter of claims 2-4 of the present application is "anticipated" by claims 3-5 of the patent, respectively.

Regarding claim 5, both the claims of the patent and the claim of the instant application recite a device for self-sampling of cervical tissue including a plurality of elongated bristles of approximately uniform length connected to a handle, where each bristle has a modulus of elasticity to form a mop-like sample head having a soft surface area. Claim 9 of the patent also provides that the plurality of bristles are *molded* with the handle, whereas claim 5 of the present application merely requires that the plurality of bristles are *secured* to the handle. Since it is well known in the art that molding bristles to a handle would be one means of securing the bristles to a handle, it can be said that claim 9 of the patent "anticipates" the broader claim 5 of the instant application. Since claim 9 of the patent "anticipates" the broader claim 5 of the instant

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application, the claims are not patentably distinct. The subject matter of claim 6 of the present application is “anticipated” by claim 10 of the patent.

10. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,387,058. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim of the instant application is merely broader than that of the patent. Both the claim of the patent and the claim of the instant application recite a device for obtaining a sample from a body cavity including a plurality of elongated bristles of approximately uniform length connected to a handle to form a mop-like sample collecting member, where the bristles are disposed in a direction parallel to the longitudinal axis of the handle. The claim of the patent further recites an annular insertion shield that is not required by claim 1 of the instant application. Claim 1 of the present application also recites that the handle includes a head portion and an elongated portion. Similar limitations are not recited in claim 1 of the patent. However, these limitations do not provide any structure to the handle of the device of the present application that defines that handle over that of the handle of claim 1 of the patent, and any handle can be said to have an elongate portion and a head portion. Therefore, claim 1 of the present application is “anticipated” by claim 1 of the patent. Since claim 1 of the patent “anticipates” the broader claim of the instant application, the claims are not patentably distinct.

Response to Arguments

11. Applicant's arguments filed November 12, 2004 have been fully considered but they are not persuasive.

Applicant contends that Bayne does not teach or suggest a "device for obtaining a sample from a body cavity" which includes "a plurality of elongated flexible bristles of approximately uniform length defining opposing first and second bristle end portions" wherein the plurality of flexible bristles "form a mop-like sample collecting member," and are supported "in a direction substantially parallel to the longitudinal axis of the elongated portion" as claimed by Applicant in Claim 1. Applicant further contends that Bayne does not teach or suggest "a brush for self-sampling of cervical tissue" which includes "a plurality of bristles of approximately uniform length," wherein "each bristle of the plurality of bristles has a modulus of elasticity to form a mop-like sampling member having a soft surface area sufficient to acquire a sample of cervical tissue" as claimed by Applicant in Claim 5. The Examiner respectfully disagrees with Applicant's contention.

Bayne teaches an exocervical cytology brush (42) that meets all of the structural limitations of the claims. In particular, the brush (42) includes a plurality of flexible bristles (50) engaged at one end thereof by a head portion (48) that is disposed on an elongate handle (46). The plurality of bristles (50) extend from a base member (head portion 48) to form a mop-like collecting member, as defined in the specification of the instant application at page 7, lines 1-2. The bristles (50) form a generally planar brushing surface and are preferably about 3/8" long (column 6, lines 8-11), indicating that the bristles are of approximately uniform length. The head portion (48) is configured to support the bristles (50) in a direction substantially parallel to the

elongated portion of the handle (Figure 3). The exocervical brush (42) is capable of being used without the endocervical brush (44). In response to applicant's argument that the Bayne reference fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the brush does not need to be precisely located) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Nevertheless, the endocervical brush might require precise location of the sampling device, but precise positioning of an exocervical brush used without the endocervical brush apparently would not be required. This assertion is supported by Bayne's teaching that the exocervical brushing surface is enabled to conform to the surface of irregularly shaped exocervix (column 6, lines 10-13). An individual would be capable of performing a self-sampling procedure with the sampling brush (42). The brush must be inserted into a body cavity in order to access the cervical tissue. The bristles (50) of Bayne are believed to have a modulus of elasticity as claimed in claim 5 of the instant application. In claim 5 of the instant application, Applicant appears to be attempting to claim a range for the modulus of elasticity where the bristles are soft on one end of the range, yet are sufficient to acquire a sample of cervical tissue on the other end of the range. However, the specification of the instant application is silent as to what particular range for the modulus of elasticity falls within the scope of the invention as claimed. In fact, the specification of the instant application fails to provide any particular dimensions for the bristles of the mop-like brush, i.e. length, modulus of elasticity, or otherwise. Since the bristles of Bayne are sufficiently stiff to acquire a sample of cervical tissue, yet are inherently soft enough to not cause excessive damage to the cervical tissue of the subject, the

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bristles of Bayne are believed to have a modulus of elasticity that falls within the bounds of the limitation as recited in claim 5 of the instant invention. Applicant's argument that Bayne's use of the word "scrape" suggests hardened bristles is not persuasive, as it is inherent that sampling bristles would not be hardened to the extent that significant trauma is caused to the cervical tissue of the subject. In view of the foregoing, the rejection of claim 1 under 35 USC 102(b) as being anticipated by Bayne ('992) is maintained, and said rejection has been expanded to encompass new claims 2-6.

12. New grounds of rejection are set forth hereinabove, citing Fomby and Peltier, to further address the amendment to claim 1 and new claims 2-6 added with the amendment of November 12, 2004.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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January 21, 2005